REMARKS/ARGUMENTS

Please note that the inventor's last name is spelled SADLOW.

Existing claims have been modified with clarifying and amplifying language and new claims added to better highlight the invention.

The outstanding Office Action utilizes the Walker U. S. Patent No. 4,435,179 to reject as obvious the originally presented claims directed to applicant's invention. Prior to analyzing the Walker disclosure and its application to the claims, attention should be directed to an overview of applicant's invention.

The invention is a low-tech system such that caregivers supervising or simply observing fluid application to a patient have a fast low cost manner means of easily observing that the level of fluid in the container is too low. There are, of course, more sophisticated, complex and expensive ways to accomplish this function, but nurses and other medical practitioners have indicated a need for a visually apparent system either as a backup or the sole monitoring means. Since monitoring is not needed in all cases of fluid administration, the system should be one that is selective and thus precludes the float being provided in all containers prior to use.

The features that enable applicant's invention to accomplish its objectives and as set forth in the claims at bar in this application include a fluid container with see-through walls and a barrier outlet seal, a cannula assembly with a tube upper end having a separable portion having a sharpened end which when passed through the barrier and entered into the container is designed to separate and float to the top of the fluid level to provide a visible fluid level monitoring float or indicator. That is, a cannula with a sharpened separable end portion originally outside the fluid container which passes through the barrier, separates and then floats to the fluid surface.

These features clearly set out in the claims are not taught, suggested or obvious from the prior art. Specifically, Walker is directed to a two-bag system where interconnection is already made and permanent by sealing the coupling 5 directly to the primary blood bag 1. Thus, the break off portion is already in the bag. Once the seal is broken, blood flows into the secondary bag 2, and the break off portion remains in bag 1. Since Walker expresses concern that the break off portion will interfere with the fluid flow from bag 1 to bag 2, Walker provides the break off portion with a shape so fluid can flow past it or he provides a pocket to contain that portion and prevent it from entering the major chamber of bag 1. Walker discusses these options as alternatives; and thus since

one of the options clearly precludes floating of the break off portion, the idea of providing a float is not part of Walker's invention. It is also at best a gratuitous statement since there is no or little need of a float to determine the level of blood—a dark red fluid easily seen by a caregiver.

What Walker is clearly interested in is providing a system in which the break off portion does not interfere with fluid flow into bag 2—nothing more. It should also be pointed out that in Walker bag 2 is the bag more likely to be used for dispensing fluid to a patient (see Lines 16 - 30, Column 1 of Walker). Thus if a float to observe fluid level was an object or consideration of Walker, the break off portion would be placed in the dispensing bag 2 or in both bags which is not the case.

Thus, it is believed clear that Walker does not teach or suggest the provision of a key point in applicant's invention—that of providing an interconnection device which includes a removable portion which acts as a float and visual safety monitor of fluid level in a dispensing bag, i.e., an I V fluid bag. Walker's gratuitous mention of plastic with a specific gravity less than that of the blood and of a colored material is simply to assure no interference with blood flow and perhaps get that portion out of the valve or transfer area. Certainly

Walker does not say or suggest establishing a visual fluid level float-monitoring indicator from the break off portion.

Another feature of applicant's invention is that the cannula assembly with the sharpened separable end is not originally part of the fluid container assembly and that the separable end not only provides the float mechanism once detached from the rest of the cannula assembly but is utilized as the piercing means by which it passes through the barrier seal into the container. The Examiner suggests that Walker does disclose that such devices are known through reference to Column 1 of Walker. This interpretation of Walker, however, is believed clearly in error. Walker in the actual language in Column 1 discusses only systems where the piercing element is part of the original fluid container system generally in the tubing which is permanently fixed between the two bags of a two-bag system,

Also, Walker refers to U. S. Patent No. 3, 110,308 to Bellamy, Jr. (copy attached). This Bellamy, Jr. patent is also directed to such a two-bag system where the connecting tube includes an internal element 22 (cannula) of steel, plastic, etc. which is transversely moveable to pierce a barrier membrane 23. None of these systems are directed to a device like applicant's where a separate cannula assembly includes a separable portion which not only pierces

the barrier but then passes into the fluid container, then separates from the remaining cannula assembly and then floats to the surface of the fluid to form a fluid level indicator.

In other words, Walker has an improvement over U. S. Patent No. 3, 110,308 and crushable tube seal systems described in Lines 50 - 60, Column 1 (see also U. S. Patent No. 4,340,049 cited as of interest). As none of the systems, which Walker refers to in his discussions of what he is improving upon, are directed to or suggest a float which can be used to monitor fluid level in a container, it is believed fair to additionally conclude that Walker is also not directed to such a purpose. Also, the systems that Walker refers to as well as Walker's system are two bag interconnected blood systems where a visual float would not be necessary due to the color of blood.

In fact, it is applicant's position that one skilled in the art reading Bellamy, Jr. and the comments set out in Column 1 of Walker would be directed away from an outside cannula system and certainly in no way suggests any cannula system in which a separable portion forms a float .

What is believed shown by the prior art is that numerous people have developed many devices somewhere near the edges of the components of applicant's invention, but no one combined all the elements together prior to

applicant despite a long standing need and the technology to accomplish such being readily available. This is believed an additive hallmark of a patentable invention.

Reconsideration and allowance of the claims at bar is requested.

Respectfully submitted,

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